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| 10/658,932  | 09/09/2003  | David N. Ku          | 9537-3              | 3113             |
| 20792 7590 03/17/2008<br>MYERS BIGEL, SIBLEY & SAJOVEC<br>PO BOX 37428<br>RALEIGH, NC 27627 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| WILLSE, DAVID H   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3738  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/658,932

**Applicant(s)**

KU, DAVID N.

**Examiner**

Dave Willse

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 and 34-73 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10-12, 27, 53-55 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 13-26, 28, 29, 34-52, 56-69, and 71-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9, 13-26, 28, 29, 34-42, 48-52, 56-69, and 71-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The examiner agrees with the Applicant that some of the originally disclosed embodiments involve a single solid (elastomeric) material that has been “frozen and thawed several times until a solid device is formed with the desired mechanical properties” (Applicant’s specification: page 12, lines 7-8). The problem is that instant claim 1 and others must be interpreted to be broad enough to encompass *other* disclosed embodiments, since otherwise the Applicant would have canceled claims 12, 16, 23, 24, 27, 29, 39, and others. Withdrawn claim 12 implies that the prosthesis can include springs and an additional elastomeric component, yet nowhere does the original disclosure teach or fairly suggest that such elements are *not* reinforcing in nature. Regarding claim 16, the original disclosure mentions *metallic* mesh along the modified, exposed surface but says nothing about *non-rigid* mesh for this feature. Regarding claim 23 and others, paragraph 0054 of the specification states that the fabric is molded *into* the device; the ordinary practitioner would have interpreted this and other passages to mean that the elastomeric component at least partially penetrates into the fabric during the molding process, and there is no indication in the original disclosure that the fabric is not a reinforcing material (even if reinforcement is not the primary

purpose of the fabric). In fact, the ordinary practitioner would have expected the fabric to provide support or reinforcement at least against tensile forces. Moreover, the fabric *itself* is part of the prosthesis as claimed, so the fabric (or at least inner volumes or regions of the fabric) is “internal” (present claim 1, line 2) relative to the *prosthesis*. It should also be pointed out that the phrase “devoid of internal reinforcing material and rigid endplates” is a dangling (or misplaced) modifier, because it appears to modify “spinal intervertebral disc” rather than “implantable prosthesis” (present claim 1, lines 1-2). Regarding claim 24, not only is the ring *within* the body of the device, but it is explicitly characterized as being a reinforcement (paragraph 0046 of the Applicant's specification). Similar problems exist with claim 27 and many others.

Because of the failure of the original disclosure to describe or even mention the negative limitations pertaining to the internal reinforcing material and rigid endplates, especially in the context of the apparently contradictory claim language discussed above, the scope of claims 1-7, 9, 13-26, 28, 29, 34-42, 48-52, 56-69, and 71-73 cannot be interpreted in light of the instant specification and is thus unsupported by the original disclosure. Because the examiner is unable to determine the metes and bounds of said claims, prior art may be applicable once the aforementioned issues have been resolved (MPEP § 2163.06). With regard to the term “monolithic”, the Applicant has invited the examiner to suggest alternative terminology (Applicant's reply of December 10, 2007: page 19, lines 14-16), but the examiner only objected to its usage in claim 47. If the core and annulus are distinct or well-defined regions of the body in terms of composition, mechanical properties, or the like, then “monolithic” is not an appropriate term and should simply be deleted from the claim. The Applicant's request for an

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interview is acknowledged, but the examiner believes that it is best for the Applicant to carefully review the above observations in conjunction with all of the rejected claims prior to making any arrangements for an interview.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman, US 7,066,960, in view of Oka et al., US 5,458,643, and Schmieding, U.S. provisional application no. 60/412,028 (via US 2004/0059425 A1). An ultimate strength in tension generally greater than about 100 kPa would have been immediately obvious, if not inherent, from the reinforcing nature of the fabric (Dickman: column 7, lines 49-55) and from the tensile strength required of a ligament (Dickman: column 10, line 6 et seq.). Since 1 N-m is a *minimal* torsion value in a range (instant claim 43, line 6), the Dickman device being capable of at least 10 degrees of rotation would likewise have been immediately obvious, if not inherent, from the fact that the implant

can resiliently absorb stresses associated with spinal rotation and the like (column 1, lines 25-30; column 5, lines 33-64; column 8, lines 49-54).

Dickman is unspecific as to the *types* of hydrogel polymers that can be used but does mention PVA hydrogel at column 4, lines 49-55, in reference to Oka et al. Since Oka et al. teach that reinforced PVA hydrogels are advantageous for both artificial articular cartilage and artificial intervertebral discs (abstract), one of ordinary skill would have been motivated to consider pertinent references in both of the related arts. Schmieding discloses that SALUBRIA, a hydrogel composition similar to human tissue in its physical properties (paragraph 0002), can be molded into anatomic shapes and is very suitable for orthopedic applications, including osteochondral implants (paragraph 0003). The Dickman hydrogel polymer being SALUBRIA would thus have been obvious to the ordinary practitioner in order to ensure reduced wear, adequate strength, and fatigue resistance (Schmieding: paragraph 0003), with further motivation being provided by the fact that all three documents are directed towards imparting sufficient strength and the like to hydrogel materials.

The upper and lower surfaces of the embodiments shown in Figures 6, 7, and 9-11 of Dickman each possess concave, convex, and substantially flat peripheral surfaces, particular when the implant is subjected to various stresses typically encountered during use (Dickman: column 8, lines 10-11), and such would also have been obvious in order to supplement fixation of the device. An anterior portion being of greater thickness than a posterior portion would have been obvious from column 8, lines 14-17, of Dickman. The further limitations of claim 44 would have been obvious to the ordinary practitioner from column 3, lines 45-50; column 6,

lines 25-33; column 8, lines 22-45; and other passages in the Dickman patent in order to facilitate osseointegration of the disc replacement.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/Dave Willse/  
Primary Examiner  
Art Unit 3738**